

## **REMARKS**

### **I. Status of the Application**

Claims 1, 3 to 6, and 9 to 29 are pending in the application. Claims 19-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, and 7 of U.S. patent 5,922,307 in view of Nakagawa, Jones, Green, Barnes and/or Sanderson. Claims 1, 3-5, 7, 8, 11, 12, 17 and 19-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 7, and 9 of U.S. patent 5,908,614 in view of Nakagawa, Jones, Green, Barnes and/or Sanderson. These rejections were made in an Office Action mailed on February 15, 2002. Applicant responded to this Office Action by virtue of an Amendment mailed on August 15, 2002 which presented amended claims and responsive arguments to the Office Action of February 15, 2002. The Examiner on September 10, 2002, mailed an Office Communication in which he indicated his belief that the Amendment of August 15, 2002 was not fully responsive to the prior Office Action for failing to include a terminal disclaimer for the '307 and '614 patents.

Applicant respectfully requests entry and consideration of the foregoing response in addition to the previous Amendment of August 15, 2002, which are intended to place this case in condition for allowance.

USSN 09/840,844  
Express mail No. EV 066773898 US

**II. Applicant's Reply of August 15, 2002, Was Fully Responsive to the Prior Office Action of February 15, 2002.**

The Examiner has contended that the Applicant's response of August 15, 2002, was not fully responsive in that there were no terminal disclaimers filed for U.S. 5,908,614 or 5,922,307. The Applicant respectfully traverses this contention.

To sustain an obviousness-type double patenting rejection, the Examiner must show that the claims of the application would be obvious over the cited references. "A double-patenting rejection of the obviousness-type is 'analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103' except that the patent principally underlying the double patenting rejection is not considered prior art." *In re Braithwaite*, 379 F.2d 594 (CCPA 1967). "Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination." *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985). The Applicant properly traversed the obviousness-type double patenting rejection on the grounds that the claims of the present invention were not obvious over the cited references.

**a. Traversal of the Obviousness-Type Double Patenting Rejection Based on the Cited Patents Being Non-Analogous Art.**

Applicant at pages 11-12 of the Amendment of August 15, 2002, responded to the obviousness-type double patenting rejection of claims 19-27 over U.S. Patents no. 5,922,307, and the obviousness-type double patenting rejection of claims 1, 3, 4, 5, 7, 8, 11, 12, 17, and 19-27 over U.S. Patent no. 5,908,614, each in view of Nakagawa et al., Jones, Green et al., Barnes, and/or Sanderson et al. The Applicant noted that each of Nakagawa et al., Jones, Green et al.,

USSN 09/840,844

Express mail No. EV 066773898 US

Barnes, and/or Sanderson et al. comprise non-analogous art and therefore cannot form the basis of a *prima facie* case of obviousness. At pages 4-6 of the Amendment of August 15, 2002, the Applicant demonstrated that Nakagawa et al., Jones, Green et al., and Barnes are nonanalogous art. "In order to rely on a reference as a basis for rejection of an Applicant's invention, the reference must be either in the field of Applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992); *In re Deminski*, 796 F.2d 436 (Fed. Cir. 1986). "[A] basis for determining whether art is analogous ... is to look at whether it deals with a problem similar to that being addressed by the inventor." *Union Carbide Corp. v. American Can Co.*, 724 F.2d 14567 (Fed. Cir. 1984).

The claims of the present application were amended in the August 15, 2002 response to clarify that the claimed composition is an orally acceptable tooth whitening peroxyacetic acid generating mixture. Each of the above-referenced patents is directed to the use of certain compositions to bleach or otherwise wash clothing or hard surfaces; *see* Amendment of August 15, 2002 at pages 6-7 and 9. As Applicant noted in the Amendment of August 15, 2002, it cannot be credibly argued that the cited patents disclosing compositions for bleaching or otherwise cleaning clothing or hard surfaces is in the same field of endeavor as orally acceptable tooth bleaching compositions; cleaning laundry is a different field of endeavor from oral care products. *C.f. Johnson & Johnson v. Kendall Co.*, 215 F. Supp. 124, 129 n.19, *rev'd*, 327 F.2d 391 (7th Cir.), *cert. denied*, 377 U.S. 934 (1964) ("cited industrial [adhesive] tapes are inapposite in the surgical field where sterilization is required"). Further, Applicant's compositions address the removal of stains from teeth within the oral cavity, and therefore must be orally acceptable

USSN 09/840,844

Express mail No. EV 066773898 US

and whiten teeth without harmful effects to the oral cavity. The compositions of the cited patents are not concerned with orally acceptable formulations or harmful effects to the oral cavity because none of the cited patents intend or otherwise suggest that it would be useful to put the compositions into one's mouth. The problems addressed by the cited patents, cleaning clothing without perhaps damage to the clothing itself, is very different from the problems faced by the Applicant, namely to whiten teeth without harmful effects to human tissue. Given the dissimilarity of the fields of endeavor and the dissimilarity of the particular problems being addressed, the cited patents cannot fairly be considered analogous art and therefore cannot support an obviousness-type rejection. See *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992) ("the combination of elements from non-analogous sources, in a manner that reconstructs the Applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness").

**b. Traversal of the Obviousness-Type Double Patenting Rejection Based on the Lack of a *Prima Facie* Case of Obviousness.**

The Applicant further responded to the obviousness-type double patenting rejection by demonstrating that a *prima facie* case of obviousness had not been stated by the Examiner. To establish a *prima facie* case of obviousness, the Examiner must show (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) a reasonable expectation of success; and (3) the prior art references must teach or suggest all of the claim limitations. M.P.E.P. 2143. In the present application, the Examiner contended that, in

USSN 09/840,844

Express mail No. EV 066773898 US

view of any of Nakagawa et al., Jones, Green et al., Barnes, and/or Sanderson et al., it would be obvious to anyone of ordinary skill in the art that the addition of glyceryl triacetate ("GTA") to expectedly boost the peroxide or peroxide precursor would not only be motivated, but there would also be a reasonable likelihood of success (emphasis in the original). Applicant at pages 11-12 of the Amendment of August 15, 2002, traversed the rejection on the grounds that it would *not* be obvious to add GTA on the basis of these patents. First, as none of Nakagawa et al., Jones, Green et al., Barnes, or Sanderson et al. are analogous art, they cannot be used to form a *prima facie* case of obviousness, as stated above. Second, in all of these patents except Nakagawa et al., the GTA is present merely as a non-aqueous solvent or as a component of a non-aqueous solvent. *See Jones*, column 2, lines 9-17 and 30 to 42, identifying the problem to be solved as that of providing a stable clothing bleach composition and that a ternary solvent mixture that includes GTA so provides; see column 3, indicating that any improvements in the stability of the solution depends on the "synergistic stabilizing effects" of the ternary solvent mixture in combination with the remaining ingredients, thus failing to teach that GTA alone would expectedly boost the peroxide or peroxide precursor; *Green et al.* at column 5, lines 50-59, identifying GTA as another liquid solvent which may be usable as a more or less suitable non-aqueous liquid medium; *Barnes* at column 2, lines 50-59, identifying GTA as an organic non-surfactant solvent of which the liquid phase is comprised; *Sanderson et al.* at column 2, lines 36-39 and 58-60, identifying GTA as a suitable non-aqueous liquid; *see also* Table 1, comparing stability results of various compositions, of which two comprise GTA and show marked differences in stability, indicating that GTA has no positive effect on the compositions. As can be seen, each of these patents identifies GTA as a minor, relatively unimportant constituent that

USSN 09/840,844

Express mail No. EV 066773898 US

on its own has no noteworthy effect. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not be based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Thus, none of these patents provide either a suggestion or motivation to modify the '307 or '614 patents by the addition of GTA; nor do they provide any indication that such a modification has a reasonable likelihood of success in boosting the peroxide or peroxide precursor; finally, they provide no indication that such a modification would result in an *orally acceptable* tooth whitening composition.

As to the Nakagawa et al. reference, Applicant noted at pages 11-12 of the Amendment of August 15, 2002 that the GTA in Nakagawa et al. is combined with an activator, namely an acetic acid ester of sugar or a sugar alcohol, to increase the water solubility and activation of the peroxide bleaching agents through a synergistic effect obtained only by virtue of the combination. Nakagawa et al. at column 2, lines 22-29. Nakagawa et al. does note that GTA has an activity of activating an inorganic peroxide bleaching agent (column 2, lines 13-16). Nakagawa et al. fails, however, to provide any suggestion or motivation that GTA could be incorporated into an orally acceptable tooth whitening composition, and no indication that such would be reasonably likely to succeed.

For these reasons, Applicant contended in the Amendment of August 15, 2002 and continues to contend that the claims of the present invention are nonobvious over U.S. Patents nos. 5,922,307 and 5,908,614, each in view of Nakagawa et al., Jones, Green et al., Barnes, and/or Sanderson et al., and that therefore the rejection on the grounds of obviousness-type double patenting over these references is improper and should be withdrawn.

USSN 09/840,844  
Express mail No. EV 066773898 US

III. **Claims 19-27 are Nonobvious over Claims 1, 4, and 7 of U.S. patent 5,922,307 in view of Nakagawa, Jones, Green, Barnes and/or Sanderson and therefore Do Not Result in Obviousness-Type Double Patenting.**

Applicant, while maintaining that the reply found in the Amendment of August 15, 2002 was fully responsive, hereby respectfully requests the Examiner to consider this supplement to the response to the obviousness-type double patenting rejection over the '307 patent in view of Nakagawa, Jones, Green, Barnes and/or Sanderson.

U.S. Patent no. 5,922,307 is directed towards improved dental compositions and methods for bleaching teeth, and more specifically towards hydrogen peroxide-containing compounds that are maintained at a substantially constant pH range of 6.0 to 10.0 during the tooth-bleaching procedure in the presence of a calcium chelating agent. See the '307 Abstract. The claims cited by the Examiner as leading to the obviousness-type double patenting rejection, claims 1, 4, and 7, each claim a method for bleaching a tooth surface comprising providing a composition consisting essentially of hydrogen peroxide and a matrix for carrying the hydrogen peroxide, the matrix having a water content greater than 70% by weight, based on the weight of the composition and further ingredients, none of which includes GTA. The claims fail to teach or suggest the use of glyceryl triacetate and fail to teach or suggest the generation of peroxyacetic acid as required by claim 19. As discussed above, none of the patents sought to be combined are properly combinable, and even were they analogous art, they do not provide a motivation to combine or a reasonable expectation of success as to the use of GTA in a tooth whitening composition. As to claim 20 of the present invention, the combined references further fail to teach a two-step process of applying one of glyceryl triacetate or a hydrogen peroxide releasing compound to a tooth surface followed by the application of the other of the two so as to generate

USSN 09/840,844  
Express mail No. EV 066773898 US

peroxyacetic acid. Similarly, claim 21 requires the separate provision of glyceryl triacetate and a hydrogen peroxide releasing compound, both in an orally safe and sufficient amount for whitening teeth, which is not taught or suggested by any of the references.

Claim 22 of the present application claims a method for cosmetically treating teeth comprising the steps of applying a source of labile acetyl groups onto the surface of a tooth, allowing the source of labile acetyl groups to penetrate into the tooth, applying a source of peroxide onto the surface of the tooth, allowing the source of labile acetyl groups to react with the source of peroxide to generate a peroxyacid within the tooth and allowing the peroxyacid to effect whitening of the tooth. Nothing in claims 1, 4 and 7 of the '307 patent suggests such a stepwise method, nor is the source of labile acetyl groups taught or suggested. Nothing in the additional references corrects this deficiency. Claims 23-27, which depend from claim 22, are therefore also nonobvious. Given the above deficiencies of the '307 patent that are not corrected by any of the remaining cited patents, alone or in combination, Applicant contends that the obviousness-type double patenting rejections of claims 19-27 over those patents in light of Nakagawa et al., Jones, Green et al., Barnes and/or Sanderson et al. are improper and should be withdrawn

**IV. Claims 1, 3-5, 7, 8, 11, 12, 17 and 19-27 are Nonobvious over claims 1, 2, 4, 5, 7, and 9 of U.S. patent 5,908,614 in view of Nakagawa, Jones, Green, Barnes and/or Sanderson and therefore Do Not Result in Obviousness-Type Double Patenting.**

Applicant, while maintaining that the reply found in the Amendment of August 15, 2002 was fully responsive, hereby respectfully requests the Examiner to consider this supplement to the response to the obviousness-type double patenting rejection over the '614 patent in view of

USSN 09/840,844

Express mail No. EV 066773898 US



Nakagawa, Jones, Green, Barnes and/or Sanderson.

U.S. Patent no. 5,908,614 is directed towards a peroxidase-activating oral care composition and methods of activating a peroxidase system that includes a non-enzymatic, water-soluble hydrogen peroxide precursor and a pH-adjusting agent capable of producing a selected pH in an aqueous solution wherein the composition facilitates the rapid release of hydrogen peroxide and results in the activation of a peroxidase enzyme in an oral cavity. *See the '614 Abstract.* The claims cited by the Examiner as leading to the obviousness-type double patenting rejection, claims 1, 2, 4, 5, 7, and 9, each claim an oral care composition or a method comprising the preparation of an oral care composition for activating a peroxidase system in an animal oral cavity comprising a non-aqueous chewable carrier, alkali metal percarbonate particles deposited on or within the carrier and acting as hydrogen peroxide precursors so as to be capable of rapidly releasing an effective amount of hydrogen peroxide, the percarbonate particles coated or encapsulated by being dispersed in a water-insoluble, non-hygroscopic, viscous fluid or in a film-forming, melt-processable waxy solid. None of the claims includes GTA. As discussed above, none of the additional patents provides the proper motivation or suggestion to use GTA in an oral cavity, and further none provides a reasonable indication of success.

Given the above deficiencies of the '614 patent that are not corrected by any of the remaining cited patents, alone or in combination, Applicant contends that the obviousness-type double patenting rejections of claims 1, 3, 4, 5, 7, 8, 11, 12, 17, and 19-27 over those patents in light of Nakagawa et al., Jones, Green et al., Barnes and/or Sanderson et al. are improper and should be withdrawn.

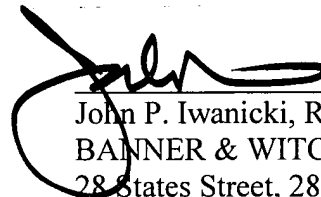
USSN 09/840,844  
Express mail No. EV 066773898 US

V. CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicant's attorney would expedite prosecution of the above-identified application, the Examiner is requested to call the undersigned at (617) 227-7111.

Respectfully submitted,

Dated: February 10, 2002



John P. Iwanicki, Reg. No. 34,628  
BANNER & WITCOFF, LTD.  
28 States Street, 28th Floor  
Boston, MA 02109  
617-227-7111

USSN 09/840,844  
Express mail No. EV 066773898 US